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10/784,088	02/19/2004	Jeffrey B. Skiba	JBS 101	7017
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MESCHKOW & GRESHAM, P.L.C. 5727 NORTH SEVENTH STREET, SUITE 409 PHOENIX, AZ 85014				
EXAMINER				
REIDEL, JESSICA L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,088

Applicant(s)

SKIBA, JEFFRY B.

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 14 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 14 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office on November 2, 2007. Claims 1-9, 12, 13, 15, 16 and 20-34 have been cancelled. Claims 10, 11, 14 and 17-19 are currently pending.

Allowable Subject Matter

2. The indicated allowability of claims 10, 11 and 16 is withdrawn in view of the newly discovered reference(s) to Anderson et al. (U.S. 2002/0182485) and Frei et al. (U.S. 5,143,079). Rejections based on the newly cited reference(s) follow.

Claim Objections

3. Claim 14 is objected to because of the following informalities: an inadvertent typographical error exists within line 9. Specifically, the Examiner suggests either deleting the phrase "to form a second fluid" since the claim previously defines this limitation. Alternatively, Applicant may change the phrase to read "to form the second fluid" instead in order clearly define that the biocompatible polymer and second element form the fluid of the second design. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. ***Claims 14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (U.S. 2002/0182485) (herein Anderson).*** As to Claim 14, Anderson discloses a method

comprising applying via screen-printing, a first fluid (i.e. AgCl conductive paste/ink conventionally used in conjunction with screen printing) to the face of a flexible non-conductive support or substrate, read as a pliable dressing material (i.e. polyethylene tape 94, 128) to form a first design 124 of an electroactive reducible material species 32 and applying via screen-printing, a second fluid (i.e. Zn conductive paste/ink conventionally used in conjunction with screen printing) to the face of the pliable dressing material 94, 128 to form a second design 120 of an electroactive oxidizable material species 34. Conventional conductive pastes/inks for screen printing inherently include a polymer. Anderson specifies that the first design 124 is a dot or oval that is physically separated from the second design 120, the second design 120 also being a dot or oval, in order to generate a voltage-potential between the designs with a coulombic capacity dictated by the minimum quantity (in equivalent weight) of Zn and/or AgCl used in each fluid forming the designs. Anderson further discloses that the first design is repeated (see, for example, element 114 of Anderson Fig. 10) and that the second design is repeated (see, for example, element 116 of Anderson Fig. 10) in order to increase the potential or voltage output produced. Anderson specifies that the first design and the second design may be repeated more than once in order to create a pattern that alternates between the first and second designs, thereby providing a wearable iontophoretic patch apparatus 110 with an increased power supply and decreased wear time. (see Anderson Abstract, Figs. 1A-1B, 9 and 10, page 1, paragraphs 2, 8-10, page 2, paragraphs 16, 17, 29 and 30, page 3, paragraphs 32 and 34 and page 4, paragraphs 43-47).

It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the pliable dressing material 94, 128 of the patch apparatus 110 of Anderson is capable of being applied to an area of

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damaged tissue. Specifically, a figure-eight-shaped foam barrier forms an absorbent cloth layer 98 applied to the back of the pliable dressing material (designated upper/inner surface of element 94 in Anderson Fig. 9 and element 128 in Anderson Fig. 10) and an elastic adhesive layer 90 is bonded to the adhesive cloth layer 98 via its coupling with material 94, 128 such that there is at least one overlapping piece of the elastic adhesive layer (see element 92 of Anderson Fig. 9 and element 130 of Anderson Fig. 10) for securing the entire patch apparatus 110, including the pliable dressing material 94 to the skin of a patient (see Anderson page 4, paragraphs 43 and 44). The Examiner notes that a recitation of the intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Accordingly, if a prior art structure is capable of performing the intended use of a claimed invention, it meets the claim. In the instant case, the overlapping portions 92, 130 of the elastic adhesive layer 90 are capable of securing the entire patch apparatus 110, including the pliable dressing material 94, 128 over an area of damaged tissue, since it may be adhesively applied to skin.

6. As to Claims 17 and 18, Anderson specifies that the first design(s) and the second design(s) “may be fabricated by conventional means using paste type materials in conjunction with well known screen printing and baking processes” (see Anderson page 3, paragraph 34). Therefore, it is inherent that the paste/inks of Anderson, as discussed above, include silver or Zn metallic powders mixed with an appropriate binder material (such a polymer) for screen-printing the designs.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. ***Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson.*** In addition to the arguments previously presented, Anderson discloses that a fine line(s) 122, 126 of conductive material (i.e. silver paste) may be printed at least partially in the spacing existing between the first and second designs and that the line(s) 122, 126 may connect to the designs (see, for example, Anderson Figs. 1A-1B and Fig. 10 and page 3, paragraph 32). Anderson discloses the essential features of the claimed invention except that the mean diameter of the dots/ovals of the first and second designs are not specified, the amount of spacing existing between each design is not specified and it is not specified that the line(s) 122, 126 comprise either of the AgCl conductive paste/ink used for printing the first design or the Zn conductive paste/ink used for printing the second design.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to make the mean diameter of the dots/ovals of the first design between about 0.5 mm and 2.5 mm, to make the mean diameter of the dots/ovals of the second design between about 0.5 mm and 4.5 mm and to make the spacing between designs between about 0.5 mm and 2.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the line(s) 122, 126 of Anderson comprise either paste/ink, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

9. ***Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Siuta (U.S. 4,540,604).*** Anderson discloses the claimed invention, as previously discussed, except

that it is not specified that the AgCl conductive paste/ink comprise at least some of silver powder particles approximately 100 microns or less in size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the AgCl conductive paste/ink of Anderson such that at least some of the silver powder particles are approximately 100 microns or less in size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In the alternative, Siuta teaches that in the art of thick-film conductor compositions for screen printing, both particle size and particle shape are very important. Siuta specifies that To attain optimum screen printing properties, it is essential that particles have a maximum particle size below 10 μm and an average particle size of 2-4 μm (see Siuta Abstract and column 4, lines 15-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the AgCl conductive paste/ink of Anderson such that at least some of the silver powder particles are approximately 100 microns or less in size as taught by Siuta, in order to improve the screen-printing of the AgCl conductive paste/ink.

10. ***Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard (U.S. 6,038,485) in view of Carrier et al. (U.S. 5,352,315) (herein Carrier) in view of Frei et al. (U.S. 5,143,079) (herein Frei).*** Axelgaard expressly discloses an apparatus 100 comprising a surface pattern of spaced dissimilar electrodes (see Axelgaard Fig. 7) comprising a first ink printed onto a primary surface of a flexible conductive film or sheet, read as an article 110 to form a first pattern comprising at least one discrete design (i.e. a spot) and printing a second ink onto the primary surface to form a second pattern that is interspersed throughout the first pattern such that elements of the first ink do not amalgamate with those of the second. The Examiner considers the first row of each of the first and third columns of spots 106 depicted in Axelgaard Fig. 7 to be the first pattern/design and the

first row of the middle column of spots 106 to be the second pattern/design. Axelgaard further discloses that the conductive inks used to print each spot may include any suitable blend of inks each including a first and second element of a conductive species (i.e. carbon or metals) and further that it may be desirable for some ink spots to have "varied conductivity" in order to tailor the current through the surface pattern of conductive electrodes. Electrode ink spots 106 having "varied conductivity" are not the same and are thus "dissimilar" (see Axelgaard column 4, lines 14-56 and column 6, lines 17-36).

Axelgaard discloses the essential features of the claimed invention except that the mean diameter of the spots of the first and second designs are not specified nor is the amount of spacing existing between each design. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to make the mean diameter of the spots of the first design between about 0.5 mm and 2.5 mm, to make the mean diameter of the spots of the second design between about 0.5 mm and 4.5 mm and to make the spacing between designs between about 0.5 mm and 2.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, Carrier teaches that the conductivity of conductive ink electrodes is impedance dependant and parameters such as ink blend and ink amount (i.e., ink thickness and ink pattern) may be varied in order to vary the impedance of a given electrode (see, for example, Carrier Abstract, column 3, lines 15-42, column 4, lines 1-44, column 6, lines 1-49, column 7, lines 41-68 and column 8, lines 1-51). Since Axelgaard specifies that it may be desirable for some ink spots to have "varied conductivity", it would have been obvious to one having ordinary skill in the art to vary/alternate either the ink blend and/or the ink thickness and pattern of the spots as is known in the art and evidenced by Carrier, in order to tailor the current through the surface pattern.

The modified Axelgaard reference discloses the essential features of the claimed invention, except that it is not specified that multiple repetitions of the first design and the second design result in at least one pattern characterized by the first design being surrounded by six hexagonally shaped dots of the second design. Frei, however, teaches that this type of hexagonal pattern for an electrode array provides for a pattern having an increased efficiency with decreased field distortion resulting from the border of the electrodes (the so-called “edge effect”). Frei teaches that hexagonal electrodes have an advantage in that they allow inter-connection for depth penetration in smaller steps versus conventional electrode arrays comprising square or circular electrodes (see Frei Abstract, Figs. 1 and 2, column 4, lines 53-62, column 5, lines 4-68 and column 6, lines 1-65). Therefore, it would have been obvious to one having ordinary skill in the art to modify the apparatus 100 taught by Axelgaard in view of Carrier and Frei such that that multiple repetitions of the first design and the second design result in at least one pattern characterized by the first design being surrounded by six hexagonally shaped dots of the second design in order to improve the electrical properties of the apparatus 100.

Response to Arguments

11. Applicant's arguments with respect to Claims 10, 11 and 14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. *Cohen (U.S. 2004/0162602)* discloses a surface electrode comprising an adhesive bandage bonded to a side of the electrode opposite the skin surface contacting side, the adhesive bandage overlapping at the perimeter in order to stick the electrode to the skin. *Leonard (U.S.*

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3,848,608) discloses a stimulator that includes a plurality of pairs of first and second immediately adjacent, noncontiguous, conductive contacts etched from conducting foil, each of the first and second contacts repeated in an alternating pattern on a flexible, insulating material to form a flexible electrodermal array. *Shoemaker, II (U.S. 5,974,344)* discloses a wound care electrode including an hydrocolloid dressing for absorbing wound seepage.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571)272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
February 8, 2008

/Kennedy J. Schaeztle/
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February 11, 2008